Appl. No.: 10/755,545

Amdt. dated August 18, 2008

Reply to Office Action of March 20, 2008

Amendments to the Claims:

- (Currently Amended) A pharmaceutical composition for the treatment and/or prophylaxis of disease associated with fibrosis in a vertebrate, said composition follistatin, or a fragment(s) or analogue thereof, and wherein said composition is provided as a dosage form comprising follistatin is present in an amount of from 0.001mg 0.001% to 5 mg 5% w/v of the follistatin composition.
- (Previously Presented) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition further comprises at least one of a pharmaceutically acceptable carrier, adjuvant and diluent.
- 3. (Original) The pharmaceutical composition of claim 2, wherein the follistatin is a single chain protein comprising between 288 and 315 amino acids with a molecular weight of between about 30,000 and 60,000 Daltons as estimated by SDS-PAGE in the absence of reducing agents, derived from follicular fluid and able to inhibit the secretion of folliclestimulating hormone (FSH).
- (Previously Presented) The pharmaceutical composition of claim 2, wherein the follistatin is a single chain protein classified as NCBI (National Center for Biotechnology Information) protein XP_003891, AAH04107 (SEQ ID NO: 1).
- 5. (Previously Presented) The pharmaceutical composition of claim 2, wherein the follistatin or a fragment(s) or analogue present in the pharmaceutical composition exists in a form selected from the group consisting of: follistatin/chelate, follistatin/drug, follistatin/prodrug, follistatin/toxin, follistatin/detector group and follistatin/imaging marker.

6.-20. (Canceled)

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21. (Original) The pharmaceutical composition of claim 1, wherein the disease associated with fibrosis is one of: a hyperproliferative or inflammatory fibrotic disease; a pulmonary fibrosis; an inflammatory bowel disease, or a related condition such as ulcerative colitis or Crobb's Disease; or liver fibrosis or cirrhosis.

 (Original) The pharmaceutical composition of claim 1, wherein the disease associated with fibrosis is liver fibrosis or cirrhosis.

23. (Withdrawn) A process for preparing the pharmaceutical composition of claim 1, wherein said process comprises homogeneously mixing at least one activin antagonist with a pharmaceutically acceptable carrier, adjuvant and/or diluent.

24.-49. (Canceled)

50. (Currently amended) The pharmaceutical composition of claim 1, wherein the dosage form comprises amount of follistatin is from 0.01mg 0.01% to 5 mg 5% w/v of follistatin the composition.

 (Currently amended) The pharmaceutical composition of claim 1, wherein the dosage form comprises amount of follistatin-is-from 0.01mg 0.01% to 2 mg 2% w/w of the follistatin composition.

52. (Currently amended) The pharmaceutical composition of claim 1, wherein the dosage form comprises amount of follistatin is from 0.1mg 0.1% to 1mg 1%-w/w of follistatin the composition.